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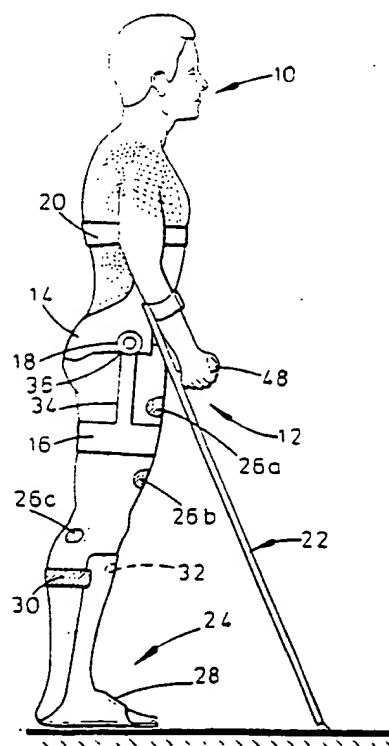
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(54) Title: ORTHOSIS AND PROSTHESIS



(57) Abstract

An orthosis or prosthesis (12) is described which has a first member (34), a second member (14) and a pivotal joint (36) therebetween. The joint (36) includes one-way clutch means based on a wrap spring clutch (42), and a servo (46) arranged to be energised to wrap or unwrap the clutch spring (42) to disengage or engage the clutch (36), the servo (46) being arranged to maintain the clutch (36) in a disengaged condition without continuing energisation of the servo. The orthosis or prosthesis can be applied to a variety of joints such as the hip, knee, ankle, elbow and wrist. Various embodiments of the invention are described.

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ORTHOSIS AND PROSTHESIS

This invention relates to orthoses and prostheses and to the control of orthoses and prostheses.

Persons may be provided with a prosthesis to replace an amputated or malformed limb, while an orthosis may be provided for use in conjunction with a limb over which some or all control has been lost, for example through spinal injury.

Orthoses and prostheses are generally constructed to mimic, as closely as possible, the natural function of a limb and thus include where appropriate various pivoting joints. The pivoting joints may be provided with clutches or the like to prevent movement in one or more directions, and pairs of joints may be linked to position limbs in relative positions similar to those experienced in natural movement: for example during gait, while one leg is being pivoted forwardly from the hip, in flexion, the other leg is being pivoted rearwardly, in extension. Also, orthoses and prostheses may be operated in conjunction with muscle over which the patient still maintains some voluntary natural control, and also in conjunction with muscle which requires external electrical stimulation by means of functional electrical stimulation (FES).

Examples of various forms of orthoses are described

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in GB-A-2 186 191, GB-A-2 206 494 A, US-A-4 697 808 and Steven E Irby's submission to the RESNA '91 Student Design Competition in March 1991.

GB-A-2 186 191 discloses a hybrid orthosis for restoring locomotion in paraplegics. The orthosis includes a hinged knee brace and electrodes which may be used to stimulate various muscles. The user is provided with a hand held control unit which is used to control the energising of the electrodes. The knee brace also includes microswitches which will sense full extension of the knee joint and thus remove stimulus once the knee has achieved full extension when the user has, for example, moved from a sitting position to a standing position. Once in the standing position, the microswitch, or other balance sensors, will sense flexing of the knee joint and, if the degree of flex reaches a level where the leg may collapse, appropriate electrodes are energised to stimulate the appropriate muscles to regain full extension. During walking, the user may manipulate the control unit to obtain appropriate flexion and extension of the knee joint through the desired gait pattern.

GB-A-2 206 494 describes a spring-assisted orthosis including means to couple a right and left leg brace together in such a way that hip flexion in either joint tends to force the other hip joint into extension, thereby providing a co-ordinating motion of the legs, assisting in producing a reciprocating gait. This reciprocating gait

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orthosis (RGO) includes a push/pull member, such as a Bowden cable, which couples the lower parts of the braces, though coupling between the braces may be disengaged for sitting.

US-A-4 697 808 disclosed an RGO in conjunction with computer controlled stimulation electrodes. The orthosis is provided with knee joints having gravity locks which lock automatically when the knee is fully extended and weight is placed on the leg. A joint unlocks when weight is shifted to the other leg and will relock following completion of a step.

Irby's submission discloses a different form of knee joint which includes a solenoid operated spring-wrap clutch which is oriented to over-run on knee extension. Clutch disengagement, by activation of the solenoid, allows knee flexion.

In GB-A-2 186 191 hip extension and pelvic stabilisation are achieved by means of selective energising of a gluteal electrode in combination with an upper thigh electrode. Such reliance on muscle stimulation may result in muscle fatigue if a user is, for example, standing for any length of time. Further, the motion of limbs achieved as a result of such electrical muscle stimulation may not coincide with the motion desired for normal gait.

In GB-A-2 206 494 the disclosed RGO enforces a rigid reciprocation between the legs of the user, quite unlike

natural gait. Also, in addition to assisting at certain times during the gait cycle, the linking of the leg braces also restricts desired leg movement at other points in the cycle, for example: after initiation of the swing phase of one leg, assisted by the link with the other leg, the natural movement of the leg would involve an acceleration, partly due to gravity, however, with the RGO, this acceleration is restricted by the link to the other leg and the friction in the link.

In US-A-4 697 808 the cable assemblies which link the hip joints are stated as maintaining an erect body posture without computer stimulation, thus avoiding the potential difficulties of GB-A-2 186 191 described above. However, the disclosed cable assemblies still suffer from the disadvantages inherent in GB-A-2 206 494, as described above.

The orthosis described in Irby's submission suffers from the disadvantage that maintaining clutch disengagement, to allow hip flexion, requires activation of a solenoid, such that any activity that requires prolonged or frequent period of clutch disengagement would require a sustained power supply which, with current technology, would require the provision of heavy batteries or frequent battery replacement or recharging.

It is among the objects of the present invention to provide orthoses and prostheses having improved performance over existing orthoses and prostheses.

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According to one aspect of the present invention there is provided an orthosis or prosthesis comprising an upper body member, a thigh member and pivotal joint therebetween, the joint including one-way clutch means arranged to permit hip extension and which may be selectively disengaged to permit hip flexion.

Preferably, the clutch means is a wrap spring clutch, and most preferably a single revolution type wrap spring clutch.

The orthosis or prosthesis may include right and left thigh members and the respective joints may be provided on the outside of the respective legs, or between the legs. When located between the legs, and when provided in the form of wrap spring clutches, the joints may include a common central hub fixed to the body member.

According to a second aspect of the present invention there is provided an orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including a wrap spring clutch and a servo which may be energised to unwrap or rewrap the clutch spring and thus disengage or re-engage the clutch, the servo being arranged to maintain the clutch in a disengaged condition without continuing energisation of the servo.

This arrangement allows control of movement at the joint with minimum power consumption and thus the weight and size of the power source for the orthosis or

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prosthesis, typically a battery pack, may be minimised.

The internal friction of the servo may be sufficient to retain the clutch spring in the unwrapped condition. Alternatively, an offset spring or a latch may be provided if the internal friction is insufficient to resist the tendency for the spring to re-wrap.

According to another aspect of the present invention there is provided an orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including energy storage means which resists pivoting of the joint in one direction and which assists pivoting in the opposite direction by energy return, wherein the energy storage means only operates over a limited degree of rotation at the joint to permit free movement over at least a portion of the pivotal movement available in said opposite direction.

The joint may be a hip joint and the energy storage means resists extension of the hip joint and assists in initial flexion of the hip joint after such extension. The energy storage means does not operate over the majority of the flexion of the hip joint and thus does not hinder such flexion. Alternatively, the joint may be the elbow, knee or ankle.

Preferably, the energy storage means is a coil spring.

According to a further aspect of the present invention there is provided a reciprocating gait orthosis comprising an upper body member, right and left thigh

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members and right and left hip joints between the upper body member and the respective thigh member, and means for coupling the right and left thigh members such that extension in one hip and thigh member forces the other and thigh member into flexion, wherein the coupling means is coupled to the hip member to permit flexion in one hip and thigh member without causing extension in the other hip and thigh member.

This arrangement permits the legs of the user a degree of independent movement, closer to natural gait. In particular, during gait, the arrangement permits the hip which has just started in extension, after heel strike, to assist in starting flexion of the other hip. After being given an initial impulse the leg in flexion may accelerate without hindrance by the coupling means and without forcing a corresponding acceleration of the leg which is in extension.

The hip joints may be provided with respective one-way clutch means operable for permitting hip flexion. Also, the coupling means may include means for energy storage such that, for example, while one hip has just started in extension the energy to be transferred to the other hip is stored in said energy storage means until the clutch means is disengaged to permit flexion of the other hip. This preferred arrangement thus provides further gait flexibility.

According to a still further aspect of the present

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invention there is provided an orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including clutch means operable to limit pivoting in at least one direction though permitting pivoting in said one direction on an application of a predetermined threshold force to said joint.

The joint arrangement assists in preventing damage to the limbs of a user or to the limbs of a prosthesis when a high level of force is applied to the members tending to pivot the otherwise locked joint in said one direction. The orthosis or prosthesis may be in the form of a hip brace operable to limit hip flexion.

The clutch means may simply slip or partially disengage on application of a predetermined threshold force to the joint, or may be partially disengaged by a clutch controller reacting to sensors provided on the orthosis or prosthesis, such as a strain gauge provided on one of the members.

The clutch means may be in the form of a wrap spring clutch which is disengaged by unwrapping the clutch spring. The degree of force necessary to overcome the clutch locking action may be decreased from a maximum by unwrapping the clutch spring a small degree. Thus, by applying a predetermined unwrapping force to the clutch spring by, for example, a tension spring, the release force of the clutch may be set at a desired magnitude.

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Where the clutch means is disengaged in reaction to force sensors, the clutch may only be disengaged while the sensors register a force being applied to one of the members above a safe threshold and thus the clutch may re-engage after the force registered by the sensors falls below the safe threshold.

These and other aspects of the present invention will now be described, by way of example, with reference to the accompanying drawings in which;

Figure 1 is a side view of a patient fitted with an orthosis in accordance with a first embodiment of the present invention;

Figure 2 is a somewhat schematic enlarged perspective view of a hip joint clutch of the orthosis of Figure 1;

Figure 3 is a state diagram of the control of sitting and standing transitions of the orthosis of Figure 1;

Figure 4 is a front elevation of a patient fitted with an orthosis in accordance with a second embodiment of the present invention;

Figure 5 is a schematic view of the hip joint of the orthosis of Figure 4;

Figure 6 is a somewhat schematic perspective view of a hip joint of an orthosis in accordance with a third embodiment of the present invention;

Figures 7, 7b and 7c are somewhat schematic end views of the hip joint of Figure 4 in various configurations;

Figure 8 is a perspective view of the hip joint of an

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orthosis in accordance with a fourth embodiment of the present invention;

Figure 9 is a schematic view of part of a reciprocating gait orthosis in accordance with a fifth embodiment of the present invention;

Figure 10 is a schematic view of a hip joint of an orthosis in accordance with a sixth embodiment of the present invention;

Figure 11 is a torque v. time graph illustrating the operation of the hip joint of Figure 10.

Figure 12 is a perspective view of an elbow control orthosis in accordance with a seventh embodiment of the present invention; and

Figure 13 is a perspective view of a hand control orthosis in accordance with an eighth embodiment of the present invention;

Figure 14 is a side view similar to Figure 1 of a patient fitted with an orthosis in accordance with a ninth embodiment of the present invention;

Figure 15 is a rear view of the orthosis shown in Figure 14;

Figure 16 is an axial section view, shown to larger scale of a wrap spring clutch/coupler mechanism used in the orthosis shown in Figures 14 and 15;

Figure 17 is a perspective view of part of the wrap spring clutch/coupler mechanism shown in Figure 16; and

Figures 18 and 19 are similar to Figures 1 and 2 and

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depict an alternative servo control structure to that shown in Figures 1 and 2.

Reference is first made to Figure 1 of the drawings which illustrates a patient 10 provided with an orthosis 12 in accordance with a first embodiment of the present invention. The orthosis 12 includes a pelvic band 14, a thigh band 16 and a pivotal hip joint 18 therebetween. The pelvic band 14 is also secured to a thoracic band 20. In most circumstances the patient is also provided with a pair of crutches 22 (only one shown). Figure 1 illustrates only the right side of the patient's body, though the orthosis is of similar configuration on the left side of the body and thus also includes a second thigh band on the left leg. The orthosis 12 is provided in conjunction with a floor reaction orthosis (FRO) 24 and a functional electrical stimulation (FES) system which includes two knee extensor electrodes 26a, 26b, and a knee flexion electrode 26c. The FRO 24 is somewhat similar to that described in GB-A-2 186 191. The FRO 24 includes a moulded plastic member 28 which receives the patient's foot and fits around the front portion of the patient's lower leg. The member 28 is secured in place by an elastic strap 30. A pressure sensor 32 is provided between the front of the member 28 and the lower leg to detect instability of the leg and cause the quadriceps to be maximally stimulated by electrodes 26a, 26b, until the pressure detected by the sensor 32 falls below a preset

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level indicating the leg is stable.

Control of movement between the member 34 connecting the thigh band 16 to the pelvic band 14 at the hip joint 18 is achieved by means of a one-way clutch, in this example a single revolution spring wrap clutch 36, which is shown in greater detail in Figure 2 of the drawings. The clutch 36 includes two hubs 38, 40, one fixed to the pelvic band 14 and the other fixed to the upper end of the thigh member 34. A wrap spring 42, of inside diameter just slightly smaller than the outside diameter of the two hubs, is forced over the hubs and secured to the fixed hub 38 by leg 39. Extension of the hip joint, that is rotation in direction A, unwraps the spring 42 such that the leg is always free to extend. However, flexion of the hip joint, that is rotation of the hub 40 in direction B, causes the spring 42 to wrap down tightly on and positively engage the hubs 38, 40. To allow flexion of the leg the spring 42 must be released and this is achieved by pulling on a control tang 44 to unwrap the spring from the hubs. In this embodiment of the invention this is achieved by means of a low power servo motor 46, such as a motor utilised in radio control models and as produced by Futaba, mounted on the pelvic band 14.

Energy consumption by the servo 46 is minimal as the internal friction present in the servo 46 is sufficient to retain the wrap spring 42 in the unwrapped condition without requiring a continuous supply of electrical power

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from the system battery.

Figure 3 of the drawings illustrates a state diagram for the orthosis 12, as operated in conjunction with a patient-controlled unit 48 (Figure 1) provided on the handle of one of the crutches. The diagram indicates the four system states, the transition conditions represented by the arrows between the system states, and the control action for the left and right legs. The condition of the hip joints is indicated by "F" and "E" representing the FREE and ENGAGED states of the wrap spring clutches 36. The arrows and the zero in the quadriceps stimulation column indicate increasing, decreasing or zero stimulus intensity. In the standing position the quadriceps stimulation is indicated by KER, this being the Knee Extending artificial Reflex, as described above with reference to the FRO 24.

Thus, in the sitting position both hip joints are free and there is no stimulation of the quadriceps. To move to the standing position the patient presses the "STAND" button on the unit 48. This engages the clutches 36 and also provides increasing stimulus for the quadriceps, which straightens the legs. Once in the standing position the clutches stay engaged and quadricep stimulation may be controlled by the pressure sensor 32 and stimulus is automatically delivered to the quadriceps whenever the pressure sensed by the sensor 32 rises above a predetermined threshold. Thus, stimulation is only

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provided when required and this reduces undue muscle fatigue. To return to the sitting position the "SIT" button on the unit 48 is pressed, decreasing the quadrilateral stimulation and freeing the spring wrap clutches 36.

While walking, the clutches 36 on the left and right leg are alternatively free and engaged depending on whether the leg is in extension or flexion, under the patient's control via the unit 48.

As described, the control signals may be derived from manually operated unit 48, however, during gait, computer pattern recognition algorithms may be utilised, in conjunction with a computer-control unit, which can detect the gait events automatically and in real time from appropriate sensor inputs which may detect insole pressures, crutch/walking aid forces, joint forces, joint movements or voice or emg signals.

Reference is now made to Figures 4 and 5 of the drawings which show a second embodiment of the present invention illustrating a patient 50 provided with an orthosis 52 which operates in a similar manner to the orthosis 12 described above, but in which the rotary joints 58, 59, analogous to hip joints, are provided between the legs of the patient. The orthosis 52 includes a pelvic band 54 and two thigh bands 56, 57 and respective thigh members 64, 65 extending up the inside of each thigh to the joints 58, 59 which are attached to the pelvic band

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54 by means of a groin tube 55.

If reference is made in particular to Figure 5 it will be noted that two wrap spring clutches 76, 77 are provided, each sharing a common fixed hub 78 and provided with a respective moveable hub 80, 81 fixed to the upper end of the respective thigh member 64, 65. Each clutch 76, 77 is operated by respective servo 86, 87 via a respective control cable 86a, 87a. The orthosis 52 is controlled in much the same manner as the orthosis 12, described above.

Reference is now made to Figures 6 and 7 of the drawings which illustrate the hip joint 90 of an orthosis in accordance with a third embodiment of the present invention. The joint 90 is provided between a pelvic band 92 and a thigh member 94 and includes a spring wrap clutch 96 operated by a servo unit 98 mounted on the band 92. The Figures illustrate the left hip joint. The clutch 96 is oriented such that the leg is free to move in extension but may only move in flexion when the clutch 96 is released. The clutch 96 and servo unit 98 are generally similar to those described above with reference to Figure 2. In addition, a tension offset spring 97 is mounted between the clutch spring 99 and the pelvic band 92. Such a spring 97 is used to hold the spring 99 unwrapped when the clutch is to be held disengaged and the force tending to re-wrap the spring is greater than the internal servo friction. Accordingly, in the absence of the spring 97,

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the servo unit 98 would require continuous energisation to maintain the clutch disengaged.

Mounted between the upper end of the thigh member 94, above the hip joint 90, is a coil spring 100 attached to the pelvic band 92 by a slider 102 which engages a post 104.

In operation, with the clutch 96 engaged such that the hip can extend but cannot flex, any hip extension beyond the neutral position (Figure 7a), in which the post 104 is at the distal end of the slide 102, will cause the spring 100 to be stretched (Figure 7b). Any energy stored in the spring 100 will be held by the clutch 96 until it is disengaged (Figure 7c). It should be noted that the spring 100 only acts over a limited range of hip joint rotation such that the spring does not impede joint rotation beyond this limited range, beyond which the slider 92 is free to move over the post 104. Typically, the spring 100 stretches over the range of approximately -10° to +15° with 0° being the neutral hip angle. This corresponds to the limit of anatomical hip joint hyperextension, as shown in Figure 7b, and if the hip joint is normal this limit is provided by the iliofemoral ligament. However, spinal cord injured (SCI) patients often have hip flexion contracture so that the limit would be provided by the stretch limit of the hip flexor muscles. It would also be possible to provide an extension limit by providing a physical stop. This range

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of movement can occur during the stance phase of standing or walking. The necessary force required to stretch the spring 100 can be provided in a number of ways: by using the musculature of the upper limbs and trunk; by stimulating paralysed hip extending muscle; or by the ground reaction force being aligned to extend the hip. The useful part of the gait cycle to release the stored energy is during the initial swing phase, this corresponding the time that the clutch 96 initially disengages. This sudden release of energy from the spring 100 assists gravity in propelling the unloaded leg forward. This appropriate and immediate force impulse at the beginning of the swing phase helps to overcome one of the limitations of FES by speeding up the gait by applying hip flexing torque before the contribution provided by the withdrawal reflex.

Reference is now made to Figure 8 of the drawings, which illustrates the hip joint 160 of an orthosis in accordance with a fourth embodiment of the present invention. The joint 160 is provided between a pelvic band 162 and a thigh member 164 and includes a spring wrap clutch 166 operated by a servo motor 168 mounted on the band 162. The Figure illustrates the right hip joint and the clutch 166 is oriented such that the leg is free to move in extension (direction E) but may only move in flexion when the clutch 166 is disengaged.

The joint 160 differs from the hip joints described

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above in a number of respects. Firstly, the thigh member 164 is mounted to the clutch 166 by a hinge 170 allowing hip abduction, and more natural leg movement. Further, the joint 160 is provided with a flexion assist spring 172 which is mounted on the band 162 and connected to the thigh member 164 by a wire 174 which passes around a band-mounted roller 176. The spring 172 is stretched during hip extension, and the resulting spring energy is released when the clutch 166 is disengaged to provide an initial impulse for hip flexion.

In this particular embodiment the clutch is retained in the disengaged condition by a latching solenoid 178. While the user is standing or walking the solenoid 178 does not operate and the solenoid plunger 180, connected to the servo crank 182, is free to move. In this particular example the servo 168 has low internal friction, and accordingly, in the absence of the solenoid 178, would have to remain energised to maintain the clutch in the disengaged condition. While the user is standing or walking an orthosis battery pack provides the necessary power. However, when the user is to be sitting for a prolonged period, with the clutch 166 disengaged, it is desirable that there is no power drawn from the battery pack. This is achieved by providing the user with a control which moves the servo crank 182 beyond the normal 'FREE' or disengaged position to a 'PARK' position. In this position the solenoid plunger 180 is attracted to an

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in-built permanent magnet in the solenoid 178, and is held in place by the magnet. The power supply to the servo may then be discontinued. To resume activity, a short pulse is passed to the solenoid 178 to free the plunger 180 from the magnet.

This embodiment further comprises an electric motor 171 mounted on the band 162 and provided with a pulley 173 from which a cable 175 extends around a pulley 177 formed on the free hub 179 of the clutch 166. The motor 171 may be selectively energised to assist in the swing phase of gait.

Reference is now made to Figure 9 of the drawings which illustrates part of a reciprocating gait orthosis (RGO). The orthosis 110 includes a pelvic band 112, right and left thigh members 122, 123 and right and left hip joints 124, 125. The movement of the thigh members 122, 123 is coupled by means of a flexible linear bearing 126, in this case a Bowdenflex (RTM) bearing. The bearing 126 is itself mounted on respective spherical bearings 128, 129 provided on the pelvic band 112 and extends around the rear of the patient's body. The central rod 130 of the bearing 126 extends from ends of the bearing sheath 132 for abutting corresponding surfaces 134, 135 provided on the thigh members 122, 123. The bearing 128 is arranged such that hip extension in one thigh member 122 forces the other hip member 123 into flexion, and thus an ipsilateral hip extending force is being used to produce a

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contralateral hip flexing force. However, hip flexion in one thigh member 122 does not cause hip extension in the other thigh member 123 as, in this embodiment, the thigh member 122 is only capable of applying a pushing force to the rod 130. This arrangement permits a degree of independent movement between the legs of the patient. In particular, during gait, the arrangement permits the hip which has just started in extension, after heel strike, to assist in starting flexion of the other hip. After being given an initial impulse the leg in flexion may accelerate without hindrance by the bearing 126 and without forcing a corresponding acceleration of the leg which is in extension.

Assistance for movement in the swing phase may be provided by means of a small d.c. motor 111 mounted on the pelvic band 112 provided with a pinion gear 113 which engages a rack 115 forming part of the rod 130.

Further flexibility may also be provided by locating energy storing means in the form of springs and the like between the ends of the rod 130 and the bearing surfaces 134, 135. When used in conjunction with a hip joint clutch this allows energy to be transferred from a hip which has just started in extension to the other hip, which energy may be stored in the spring until the clutch is disengaged to permit flexion of the other hip.

Reference is now made to Figures 10 and 11 of the drawings which illustrate features of a fifth embodiment

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of the present invention. Figure 10 shows part of an orthosis including a hip joint 140 provided between a pelvic band 142 and a thigh member 144. As with the other embodiments described above, movement of the hip joint 140 is controlled by means of a wrap spring clutch 146 operated by means of a servo 148. Further, a strain gauge 150 is mounted on the thigh member 144 and is used to measure the torque being generated by the clutch 146. This torque, after being amplified by amplifier 151, is compared against a set point, which can be varied, and if the error detected by a comparator 152 is such that the clutch torque is less than the set point the clutch 146 will remain fully engaged. However, if the detected error is such that the generated torque exceeds the set point then the servo motor 148 moves the controlled tang 154 of the clutch 146 in a direction tending to reduce the friction between the wrap spring and the clutch hubs. This allows pivoting of the hip joint 140 causing the measured torque to fall below the set point which in turn causes the servo 148 to move the control tang 154 in a direction causing increased engagement. In this way the torque output will remain approximately at the set point during periods when the external torque would otherwise exceed this level, as shown in Figure 11.

This system may be used to avoid dangerous loads being transmitted to the bones of the patient fitted with the orthosis, or in preventing damage to a prosthesis.

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In Figure 10 a cable is shown between the servo 148 and the control tang 154, although an eccentric cam could be mounted on the servo to effect movement of the tang 154.

Although all of the orthoses described above feature a clutch at a hip joint, it will be clear to those of skill in the art that a similar effect may be achieved at any appropriate joint on the body. Reference is now made to Figure 12 of the drawings which illustrates an elbow control orthosis 190 in accordance with a seventh embodiment of the present invention. The orthosis 190 includes upper and lower arm members 192, 194 including respective mounting collars 196, 198 which retain the orthosis on the arm. Two pivot joints 200, 202 are provided between the members 192, 194 and one of the pivot joints 200 is provided with a wrap spring clutch 204. In this particular orthosis the clutch 204 is oriented to prevent elbow flexion when engaged. In this particular example the clutch 204 is manually controlled by the user, by means of a string 206 which extends between the clutch control collar 208 and a ring 210 on one of the fingers. A coil spring 212 is provided and extends between the arm members 192, 194 and tends to flex the elbow.

This orthosis 190 is useful in assisting patients having impaired control of an upper limb due to, for example, quadriplegia or head injury. In this particular example the patient has no control of biceps, that is she cannot hold weighty objects against gravity but can extend

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the elbow joint. She also good wrist and hand control. The elbow flexing spring constant is selected to suit the patient to provide sufficient tension to hold the heaviest object while permitting the patient to extend the elbow against the spring 212. To pick up an object, up the clutch 204 is disengaged so the patient is able to extend her elbow, against the spring 212, grasp the object and using voluntary control over her triceps allow the spring 212 to bring up the object to the desired position. To hold in this position, the patient then engages the clutch 204, preventing further flexion and allowing the patient to relax her triceps. With the clutch 204 in the engaged state the patient can extend her elbow using her triceps at any time.

Although in this embodiment the clutch 204 is manually operated by means of the string 206 the clutch 204 may of course be actuated by a servo motor controlled by switches, sip/puff switches, voice, movement or emg signals. Further, although in the example described patient has good control of triceps and other wrist/hand muscles in some patients with more extensive paralyses FES could be used to provide similar actions of the paralysed muscles. Again, when holding the object the necessary forces and reactions are provided by the spring 212 and the clutch 204 so that muscle fatigue is avoided.

Reference is now made to Figure 13 of the drawings which illustrates a hand control orthosis in accordance

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with an eighth embodiment of the present invention. Such an orthosis 220 is used to control hand grip if a patient has weak hand grip or a hand grip which cannot be sustained for any length of time. The orthosis 220 includes a wrist member 222 in the form of a collar. The orthoses 220 also includes a glove 224 which provides mounting for guides 226, 228 for location on the inside and outside of the hand, respectively. The inner guides 226 provides mounting for a semi rigid rod 230 which is pivotally attached to a crank 232 mounted on a hub of a wrap spring clutch 234 with a fixed hub mounted on the wrist member 222. Control of the clutch 234 is achieved by means of a servo motor 242. Retraction of the rod 230 tends to flex the fingers, while extension of the rod tends to extend the fingers. The outer guides 228 provide mounting for an extension cable 236 which is attached, via a coil spring 238 and posts 240, to the wrist member 222.

To grip an object, the clutch 234 is disengaged, the fingers are extended under the influence of the spring 238 and then the object is gripped as tightly as required. The clutch 234 is then engaged to prevent extension and allows the patient to hold the object with no further muscle activity.

Although the orthosis 220 described includes a servo controlled clutch, the clutch may also be controlled using a cable and ring arrangement such as described with reference to Figure 12. Further, in the case where the

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flexors of the hand are too weak or paralysed, FES may be used to provide flexion if suitable control sites are available.

Although described above only with reference to orthoses, it will be clear to those of skill in the art that the various aspects of the present invention are equally applicable for prosthetic applications. In upper limb prosthetics aspects of the present invention are particularly useful for minimising power requirements for prostheses during extended gripping or object holding or carrying activities. For above elbow amputees, elbow control may be enhanced by including a wrap spring clutch in the elbow joint. Electric motors may be used to position the elbow with the clutch disengaged. When it is required to hold a heavy weight with the elbow flexed the clutch may be engaged to prevent extension and battery power to the motors may be switched off. For prosthetic hand grip control a wrap spring clutch could be positioned in either the joint of the thumb and/or the joints of the fingers. With the clutch disengaged the electric motors, or body movements such as the contralateral shoulder movement transferred through a Bowden cable, may be used to extend and flex the fingers to grip the object. The clutch is then engaged to prevent extension and battery power to the motors may be switched off. The object can then be gripped or carried indefinitely without consuming battery power. Control signals can be derived from

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contralateral movements or from other controls such as described above with reference to Figures 12 and 13.

Reference is now made to Figures 14 and 15 of the drawings in which the lateral thigh uprights 300, 302 from thigh cuffs 304, 306 pivot through a tubular-shaped wrap spring clutch/coupler mechanism generally indicated by reference numeral 308 contained in housing 309 which, in use, is located across the small of the patients back. The lateral thigh uprights 300, 302 have horizontal portions 310, 312 respectively connected to a coupler tooth mechanism best shown in Figure 16. The toothed coupler 314 has two parts 316, 318 connected to portions 310, 312 respectively via wrap spring clutches 320, 322 respectively. Coupler part 318 moves with left shaft 312 and can slide axially to the left to disengage from part 316, but is maintained in the engaged position shown by coil spring 324. Coupler part 316 is fixed to shaft 310, as indicated by screwhead 326.

With the coupler 314 in the position shown in Figure 16 both shafts 310, 312 are mechanically fixed together and therefore rotate together. Thus flexion on the right leg is mirrored by flexion on the left leg; the same applies for extension. The coupler 314 is in this position when the patient is using the swing through gait. That is, when both legs are required to flex and extend together by FES induced muscle contractions. The coupler 314 ensures that the legs move exactly together.

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The coupler 314 can be disengaged by manually moving the slider 326 to the left. This slides the toothed part 318 of the coupler 314 along the left shaft 312 and the coupler 314 disengages. In this position, and with wrap spring clutches 320, 322 in a 'free' position, left and right shafts 312, 310 rotate independently. That is, the left and right legs can move independently. The coupler 314 is in this position when the patient performs other gait modes such as reciprocal walking.

Each wrap spring clutch (WSC) 320, 322 is coupled to a servomotor 328, 330 (Futaba Corporation) which controls the operations of WSC's 320, 322 as will be discussed with reference to Figure 17 as well as Figure 16. Only WSC 320 will be discussed in detail.

A plastic collar 332 is loosely fitted over the drive spring 324 and a control tang 334 locates in a small slot 338 as shown in Figure 17. In Figure 17 the two hubs forming the WSC have been removed in the interest of clarity. The plastic collar 332 has a flat ridge 340 and the output of the servo motor 330 connects with an eccentric cam 342 which can rotate against the ridge 340 of the plastic collar 332 as shown. Thus as the servo 330 rotates the cam 342 this, in turn, rotates the plastic collar 332 which, in turn causes the plastic collar 332 to displace the control tang 334 of the drive spring 324 of the WSC 320. Displacing the control tang 324 of the drive spring controls the action of the WSC 320. If the control

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tang 334 is in its relaxed position the WSC 320 is engaged and will only allow rotation in the opposite direction to the wrap of the drive spring 324. If the plastic collar 332 is rotated and the drive spring control tang 334 displaced, tending to unwrap the spring off the hubs, the shaft 312 (fixed to one of the WSC hubs) will become free to rotate in either direction.

The left WSC 322 controls the motion of left shaft 312 and the right WSC 320 controls the motion of the right shaft 310. Each shaft 310, 312 passes through its corresponding WSC 320, 322. One hub of each WSC is fixed to its shaft 310, 312 respectively as shown (fixture is indicated by a slotted screwhead in Figure 16). The other hub 348 into which the end of the drive spring 324 locates (the opposite end to the control tang 334) is fixed to the tubular casing 309 as shown in Figure 16.

With the coupler 314 disengaged the rotation of each shaft is controlled by the state of the WSC's 320, 322. As described elsewhere during swing phases of reciprocal gait the WSC's 320, 322 are "free" and is "engaged" during stance phases.

With the coupler 314 engaged both left and right shafts 310, 312 move together. Motion can be controlled by either or both WSC's 320, 322. This mode would be used for swing through gait and typically the WSC's would be operated together such that they were free during swing and engaged during stance phases.

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In the simplest arrangement for all gait modes, both left and right WSC's 320, 322 are free during walking and are both engaged whilst standing still to prevent bilateral flexing at the hips. In this arrangement the function of the brace during swing is limited to guiding the legs and preventing the swing leg(s) crossing.

Figures 18 and 19 show an alternative servo control of a WSC similar to that shown in Figures 1a and 2 and like parts are referred to by like numerals in the interest of clarity where the servo motor 46 is coupled to the control tang 44 of WSC 42 by a lever 47, which is also a valid way of positioning the WSC 42 and controlling displacement of the tang 47 by the servo motor 46.

The figures of the described embodiments show a two-part orthosis with no mechanical linkage crossing the knee. The same arrangement could also be used with standard leg braces (Knee Ankle Foot Orthosis KAFO's) including lockable knee joints.

With regard to Figures 14 to 17, if only the "swing through" gait mode is required, the coupler 314 could be eliminated and the left and right shafts 310, 312 combined into a single shaft. The device could be further simplified by removing one of the WSC's and associated servo since this is now redundant.

In lower limb prosthetics, wrapped spring clutches may be used for preventing unwanted flexion at the hip, knee or ankle joints, and as wrap spring clutches are

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largely self energised minimal battery power is required for their operation. In a hip disarticulation prosthesis a wrap spring clutch can be included in the hip joint and switched between the disengaged and engaged states to correspond with flexion and extension respectively. For the above knee amputee a wrap spring clutch may be included in the knee joint and switched between the disengaged and engaged conditions corresponding with the flexion and extension phases of gait. In the ankle joint of a prosthesis a wrap spring clutch allows the angle of dorsiflexion stop to be altered. Thus, the stop may be neutral for normal walking and dorsiflexed for slope or step negotiation. Further, in some cultures it is useful to have a free ankle for squatting and including a wrap spring clutch in the joint axis allows the effective stop to be changed electronically. To squat the clutch would be disengaged, for the walking the clutch would be engaged in the neutral position (0°) to prevent further dorsiflexion and for slopes/stairs the clutch may be engaged at 10° dorsiflexion to prevent further flexion. To control this action a goniometer would be included in the ankle joint to indicate to the clutch servo controller the appropriate times to switch state.

It will also be clear to those of skill in the art that in many aspects of the present invention a variety of motion control devices, other than the preferred wrap spring clutch, could be utilised, for example: friction

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plate brake/clutches; magnetic particle brakes; friction drum brakes; hydraulic dampers; pneumatic cylinders; and electric motors. Each of these devices, and wrap spring clutches if desired, may be coupled to the respective joint using gearing drives such as spur gears, belt or chain drives, planetary gears or linear ball screws. However, the preferred wrap spring clutch provides for a high holding torque for a relatively small clutch size permitting direct coupling to the respective joint.

CLAIMS

1. An orthosis or prosthesis comprising an upper body member, a thigh member and pivotal joint therebetween, the joint including one-way clutch means arranged to permit hip extension and which may be selectively disengaged to permit hip flexion.

2. An orthosis or prosthesis as claimed in claim 1 wherein the clutch means is a wrap spring clutch.

3. An orthosis or prosthesis as claimed in claim 1 or claim 2 wherein the wrap spring clutch is a single revolution type wrap spring clutch.

4. An orthosis or prosthesis as claimed in any preceding claim wherein the orthosis or prosthesis includes right and left thigh members and the respective joints are provided on the outside of respective legs or between the legs.

5. An orthosis or prosthesis as claimed in claim 4 wherein when located between the legs and when provided in the form of a wrap spring clutch, the joint may include a common central hub fixed to the body member.

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6. An orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including a wrap spring clutch and a servo which may be energised to unwrap or rewrap the clutch spring and thus disengage or re-engage the clutch, the servo being arranged to maintain the clutch in a disengaged condition without continuing energisation of the servo.

7. An orthosis or prosthesis as claimed in claim 6 wherein an offset spring or latch is provided to resist the tendency for the spring to re-wrap.

8. An orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including energy storage means which resists pivoting of the joint in one direction and which assists pivoting in the opposite direction by energy return, wherein the energy storage means only operates over a limited degree of rotation at the joint to permit free movement over at least a portion of the pivotal movement available in said opposite direction.

9. An orthosis or prosthesis as claimed in claim 8 wherein the joint is a hip joint and the energy storage means resists extension of the hip joint and assists in initial flexion of the hip joint after extension.

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10. An orthosis or prosthesis as claimed in claim 9 wherein the energy storage means is a coil spring.

11. A reciprocating gait orthosis comprising an upper body member, right and left thigh members and right and left hip joints between the upper body member and the respective thigh member, and means for coupling the right and left thigh members such that extension in one hip and thigh member forces the other and thigh member into flexion, wherein the coupling means is coupled to the hip member to permit flexion in one hip and thigh member without causing extension in the other hip and thigh member.

12. A reciprocating gait orthosis as claimed in claim 11 wherein the hip joints are provided with respective one-way clutch means operable for permitting hip flexion.

13. A reciprocating gait orthosis as claimed in claim 11 or claim 12 wherein the coupling means includes means for energy storage such that while one hip has just started in extension the energy to be transferred to the other hip is stored in said energy storage means until the clutch means is disengaged to permit flexion of the other hip.

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14. An orthosis or prosthesis comprising a first member and a second member and a pivotal joint therebetween, the joint including clutch means operable to limit pivoting in at least one direction though permitting pivoting in said one direction on an application of a predetermined threshold force to said joint.

15. An orthosis or prosthesis as claimed in claim 14 wherein the joint arrangement assists in preventing damage to the limbs of a user or to the limbs of a prosthesis when a high level of force is applied to the members tending to pivot the otherwise locked joint in said one direction.

16. An orthosis or prosthesis as claimed in claim 14 or 15 wherein the orthosis or prosthesis is in the form of a hip brace operable to limit hip flexion.

17. An orthosis or prosthesis as claimed in any one of claims 14 to 16 wherein the clutch means slips or partially disengages on application of a predetermined threshold force to the joint, or is partially disengaged by a clutch controller reacting to sensors provided on the orthosis or prosthesis.

18. An orthosis or prosthesis as claimed in claims 14 to 17 wherein the clutch means is in the form of a wrap

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spring clutch which is disengaged by unwrapping the clutch spring.

19. An orthosis or prosthesis as claimed in claims 14 to 18 wherein the clutch means is disengaged in reaction to force sensors, the clutch is only be disengaged while the sensors register a force being applied to one of the members above a safe threshold and thus the clutch re-engages after the force registered by the sensors falls below the safe threshold.

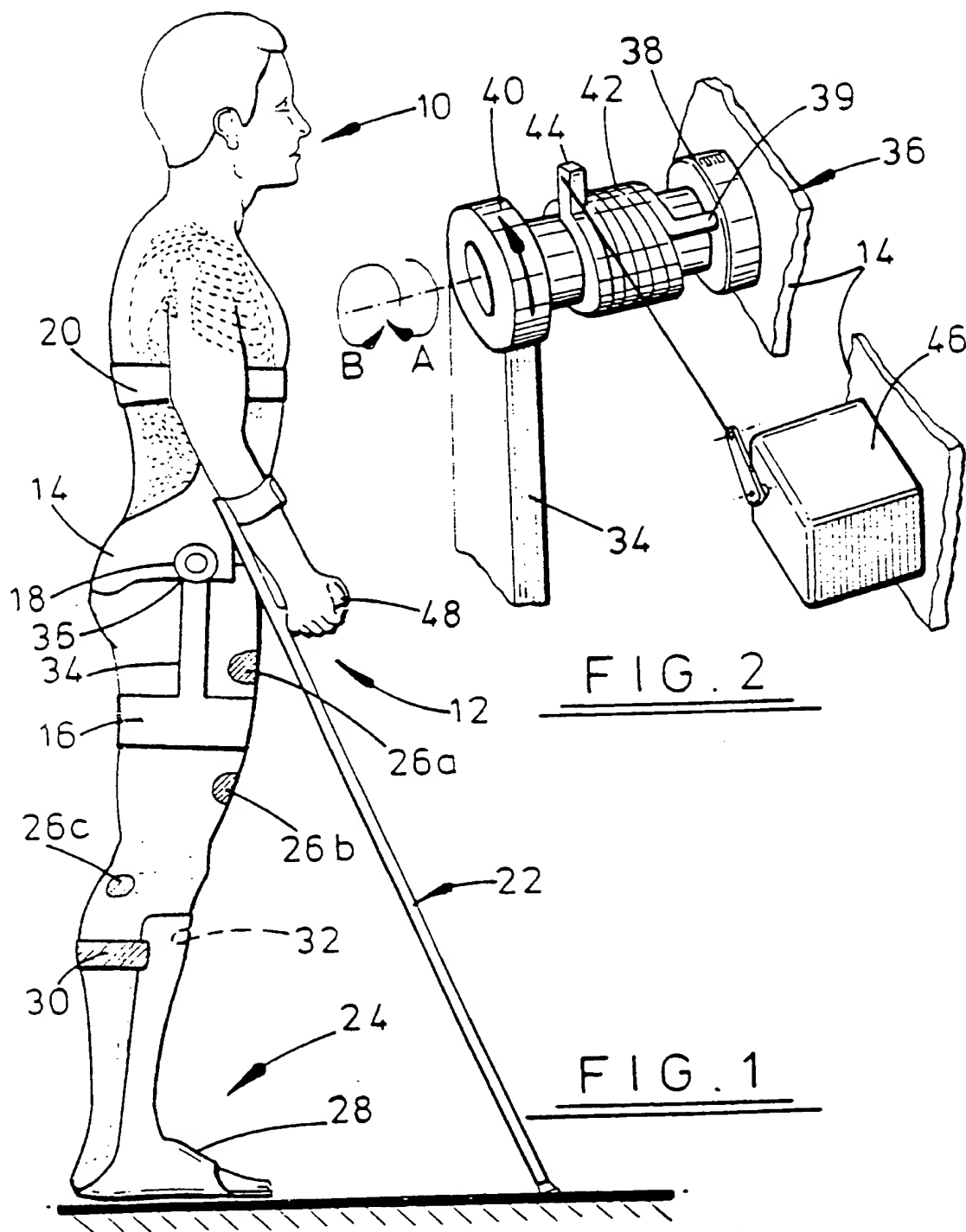
20. An orthosis or prosthesis comprising a first member and a second member coupled by a mechanical coupling, control means for actuating said mechanical coupling to provide for swing through gait.

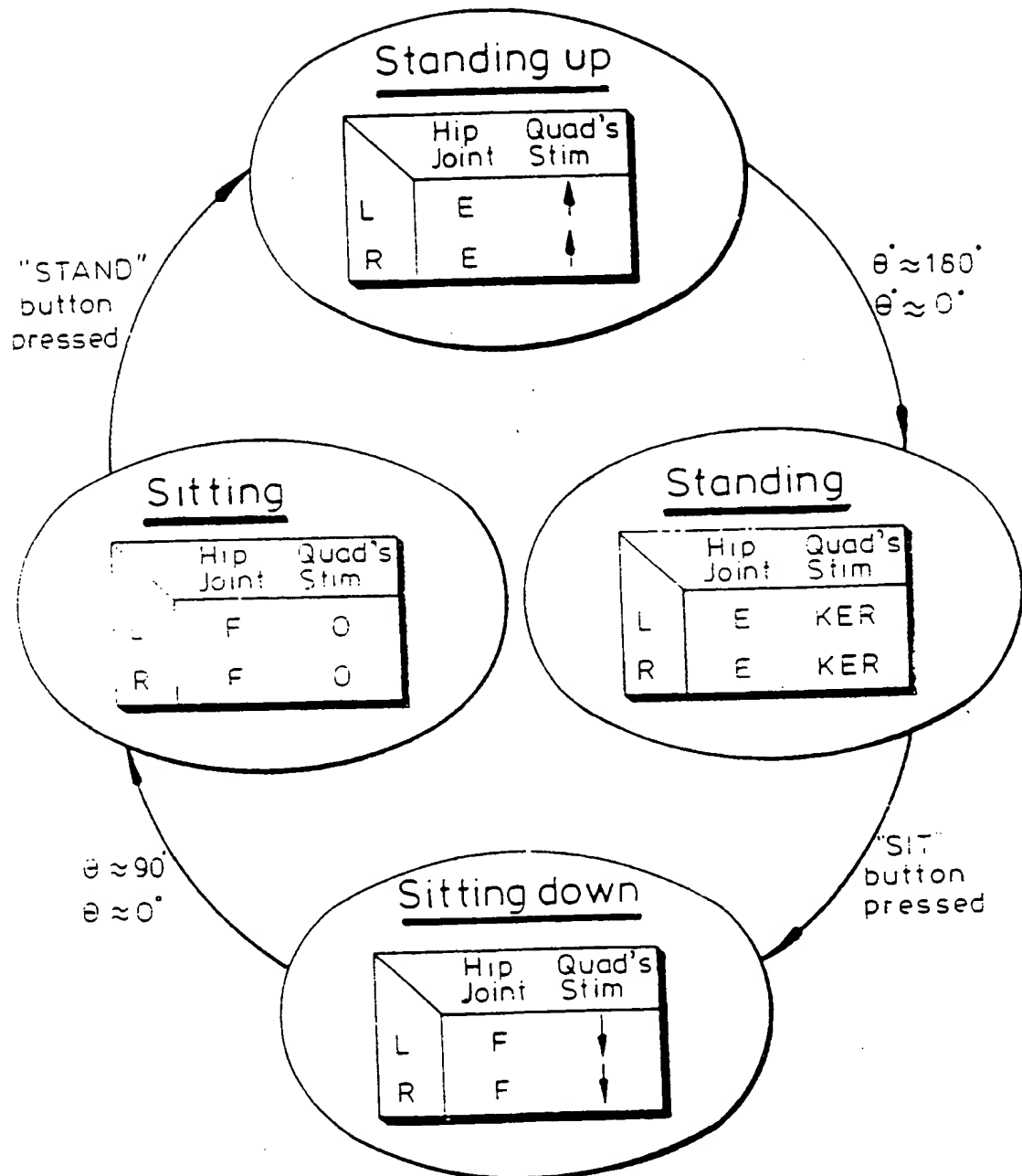
21. An orthosis or prosthesis as claimed in claim 20 wherein said coupling includes a servo actuated wrap spring clutch.

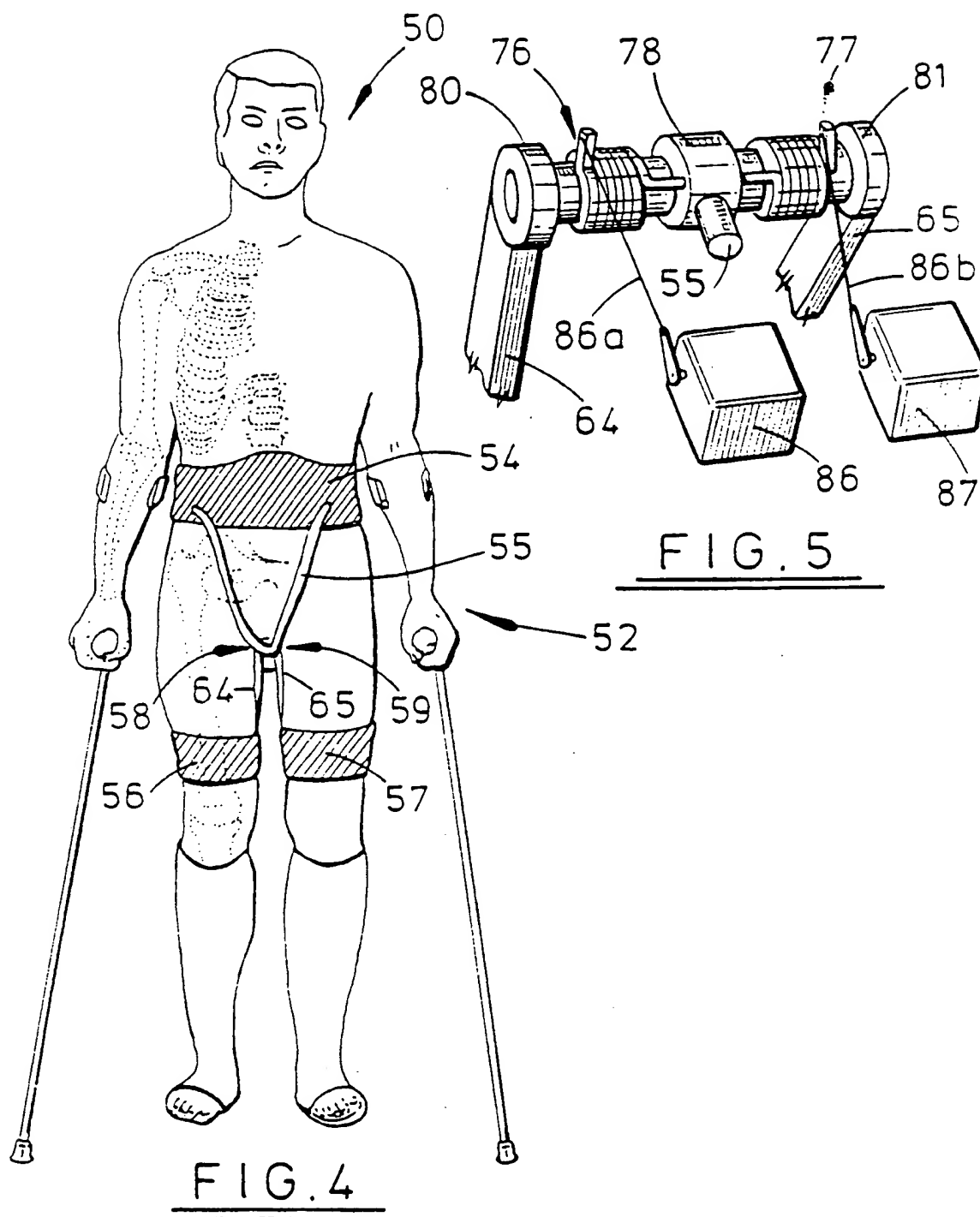
22. An orthosis or prosthesis as claimed in claim 20 wherein a coupling element is used in combination with the coupling means, said coupling element being actuatable to allow swing through gait or reciprocating gait to occur.

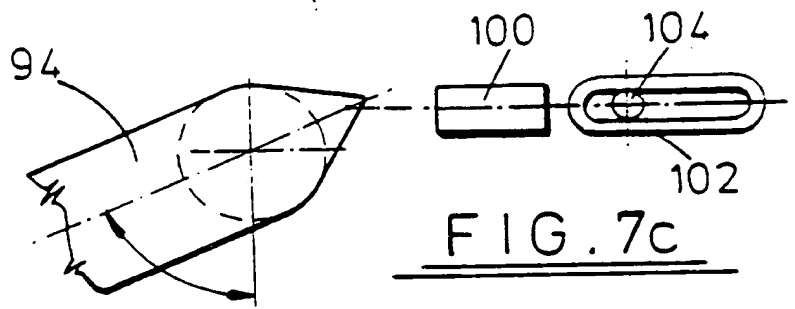
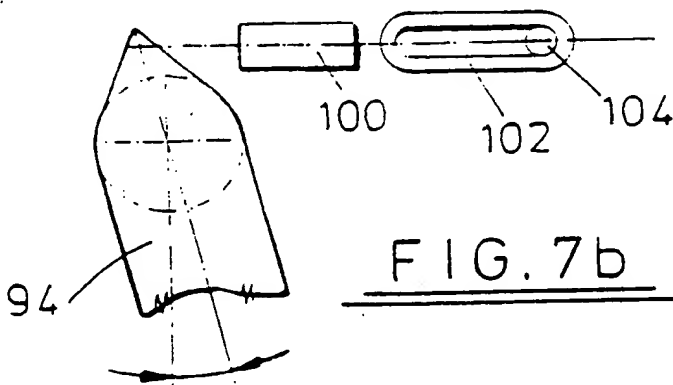
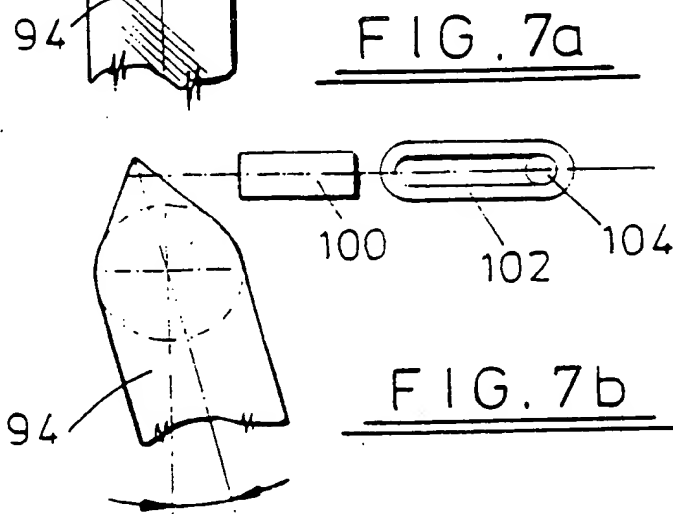
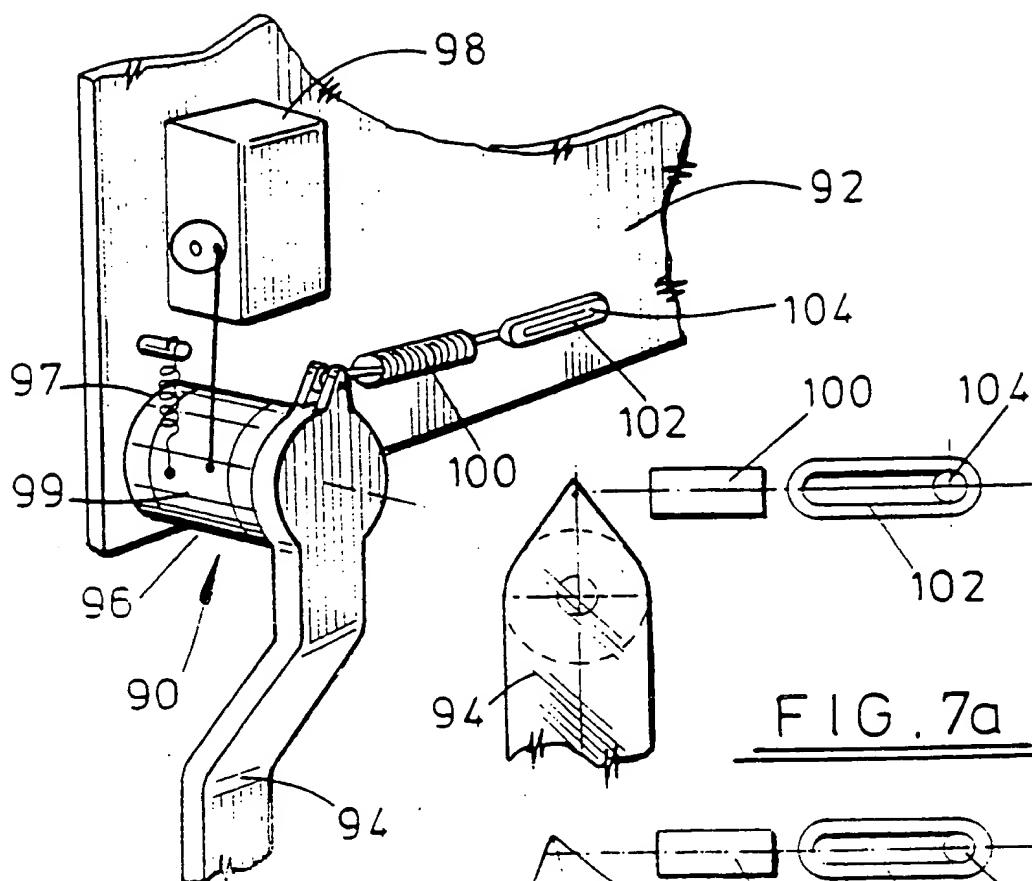
- 37 -

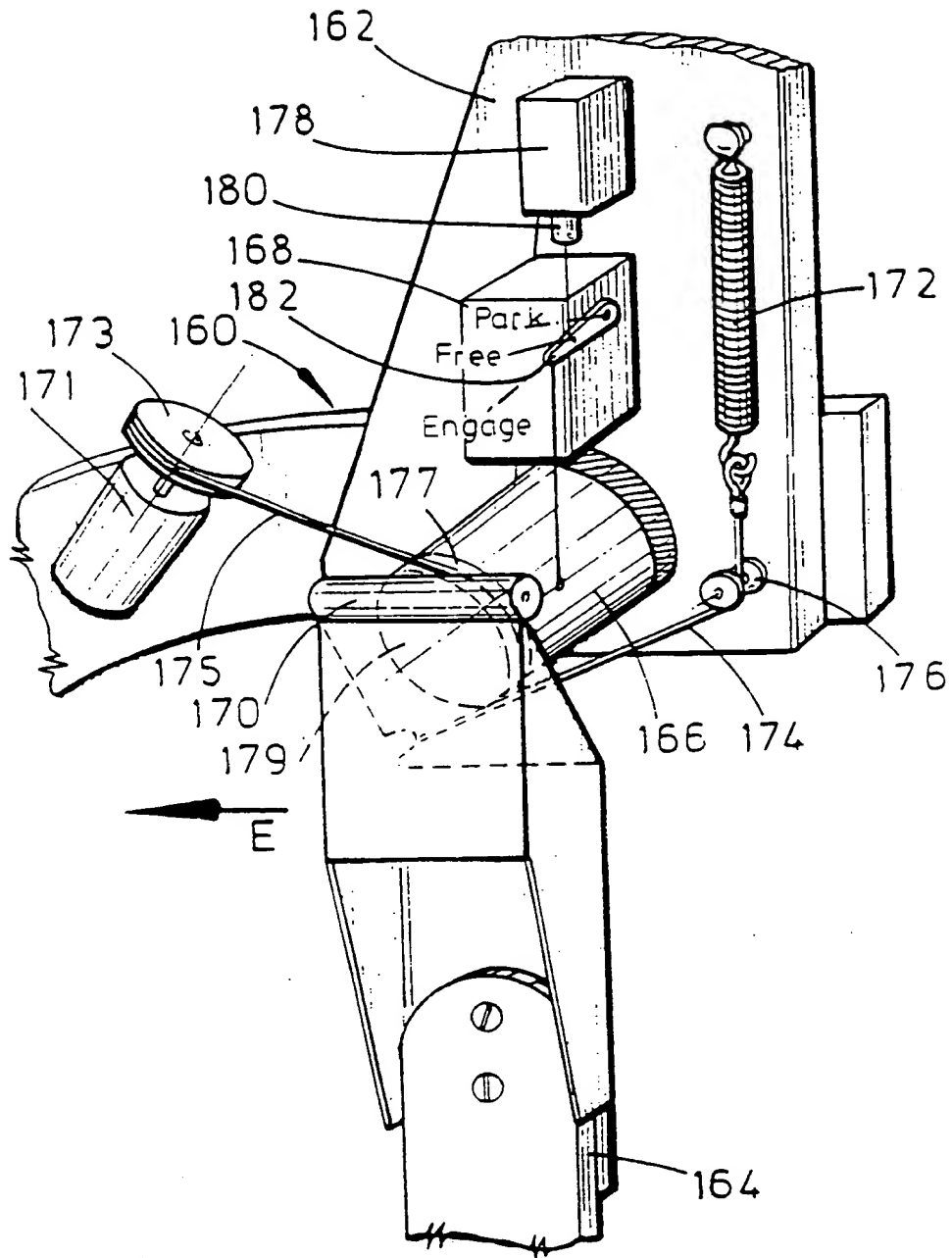
23. An orthosis or prosthesis as claimed in claim 22 wherein first and second shafts are connected to respective first and second members and the coupling element is connected to said first and said second shafts, and a wrap spring clutch being coupled to each of said first and said second shafts.

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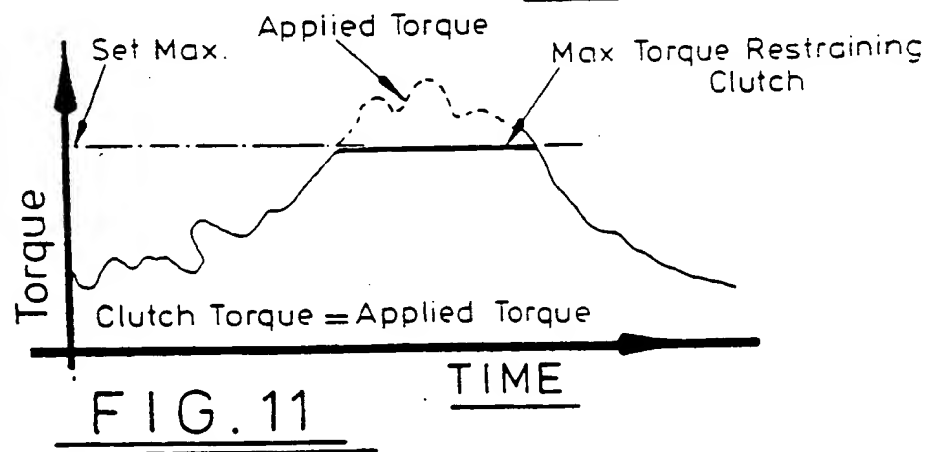
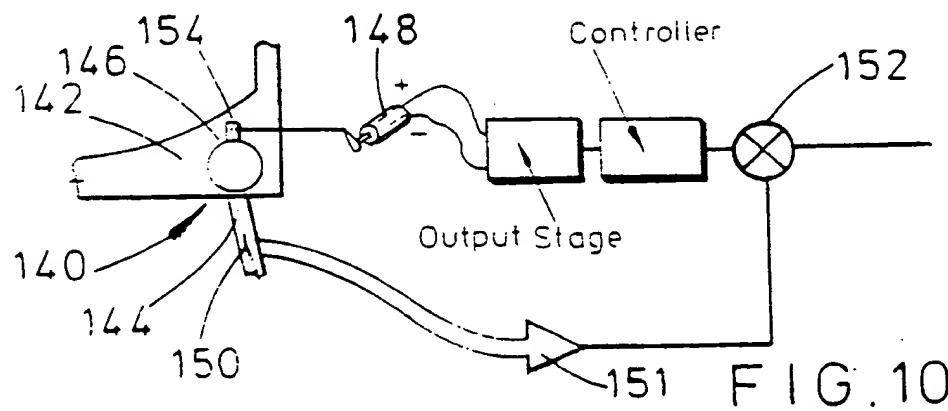
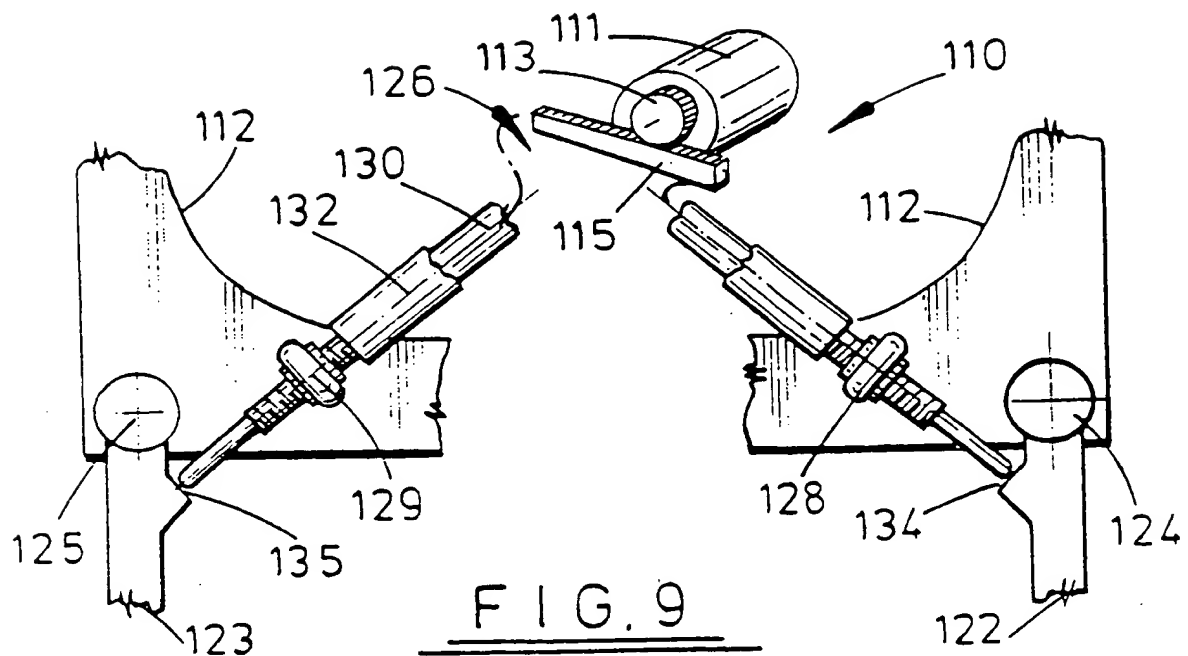
2/10FIG. 3

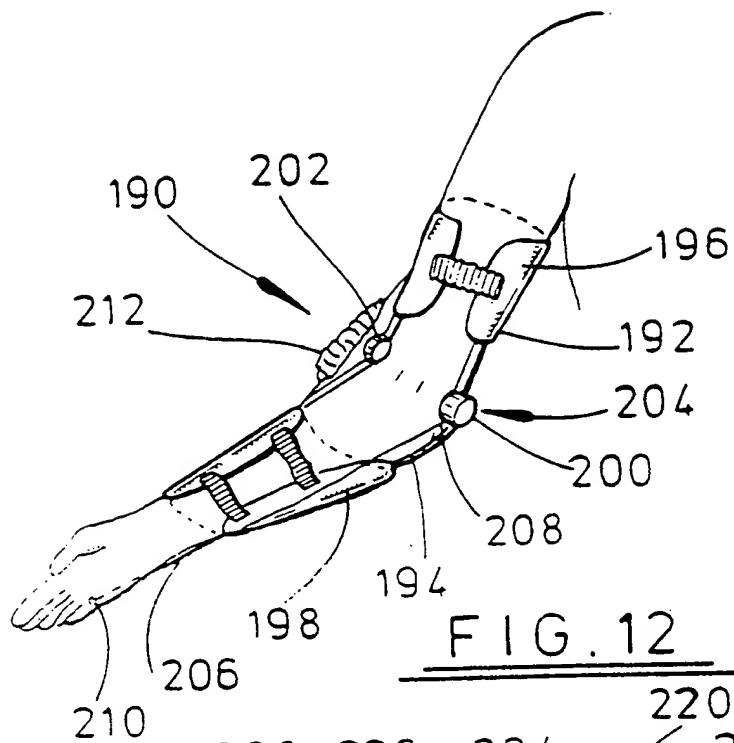
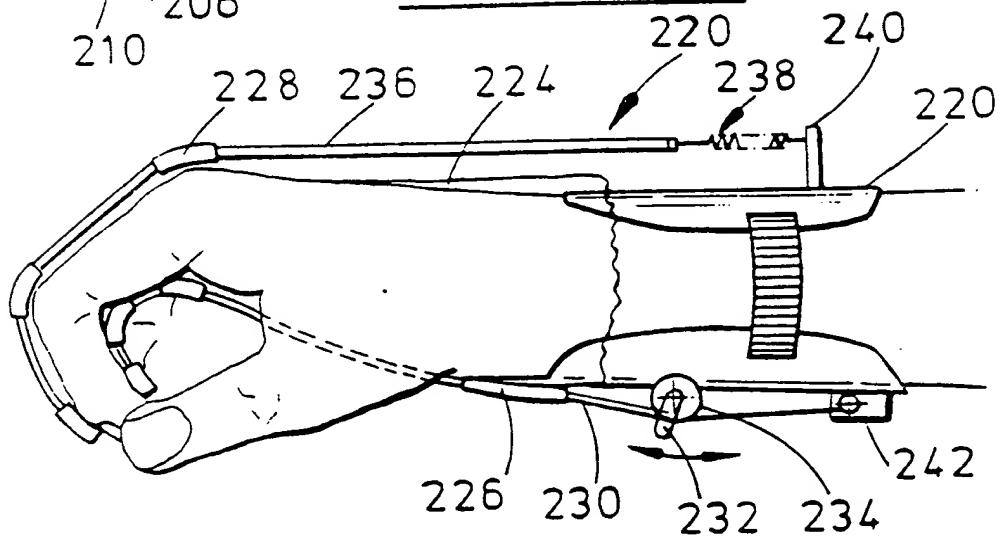
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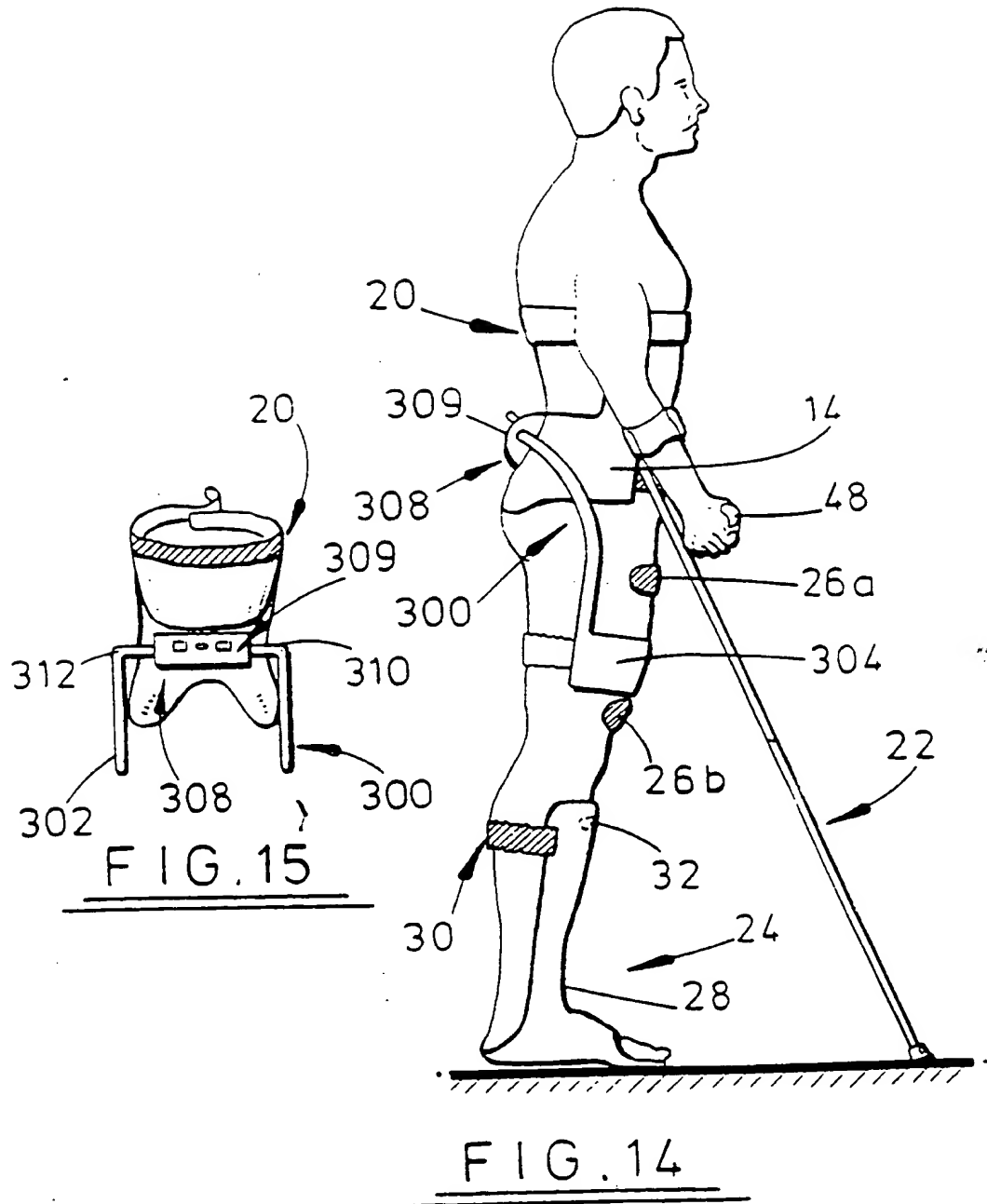


5/10FIG. 8

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7 / 10FIG. 12FIG. 13

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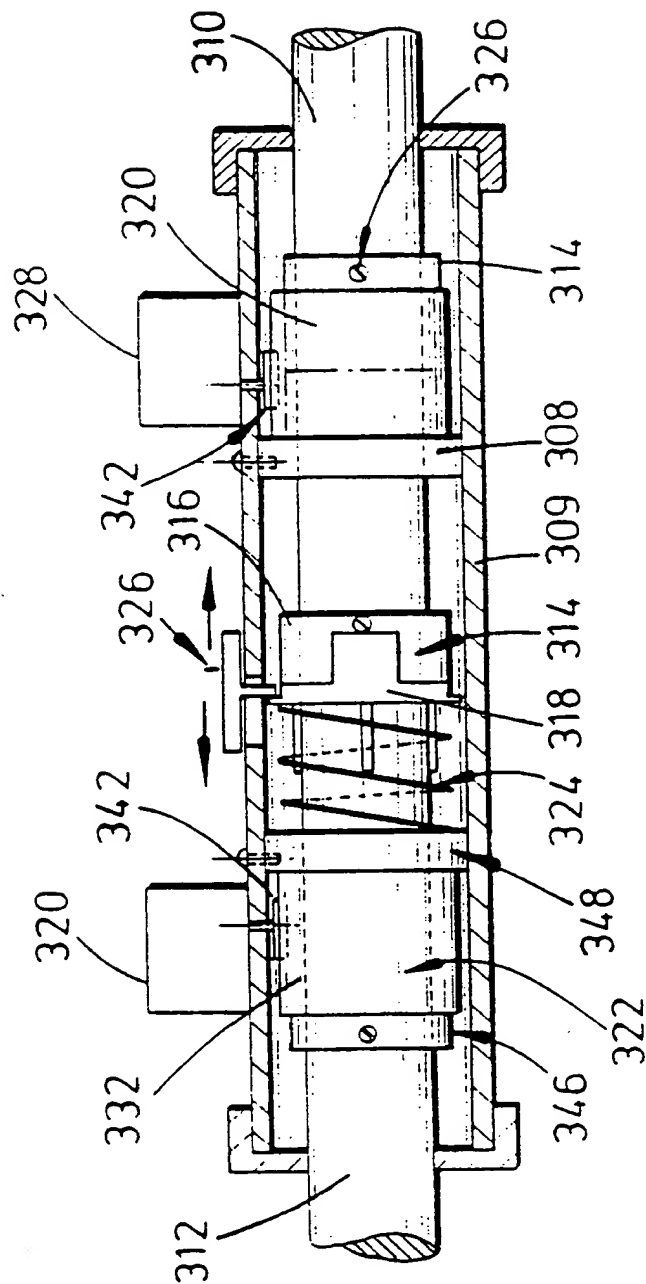
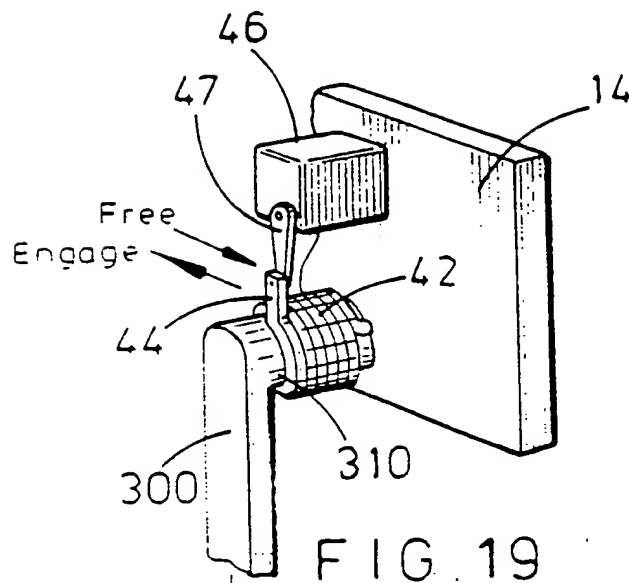
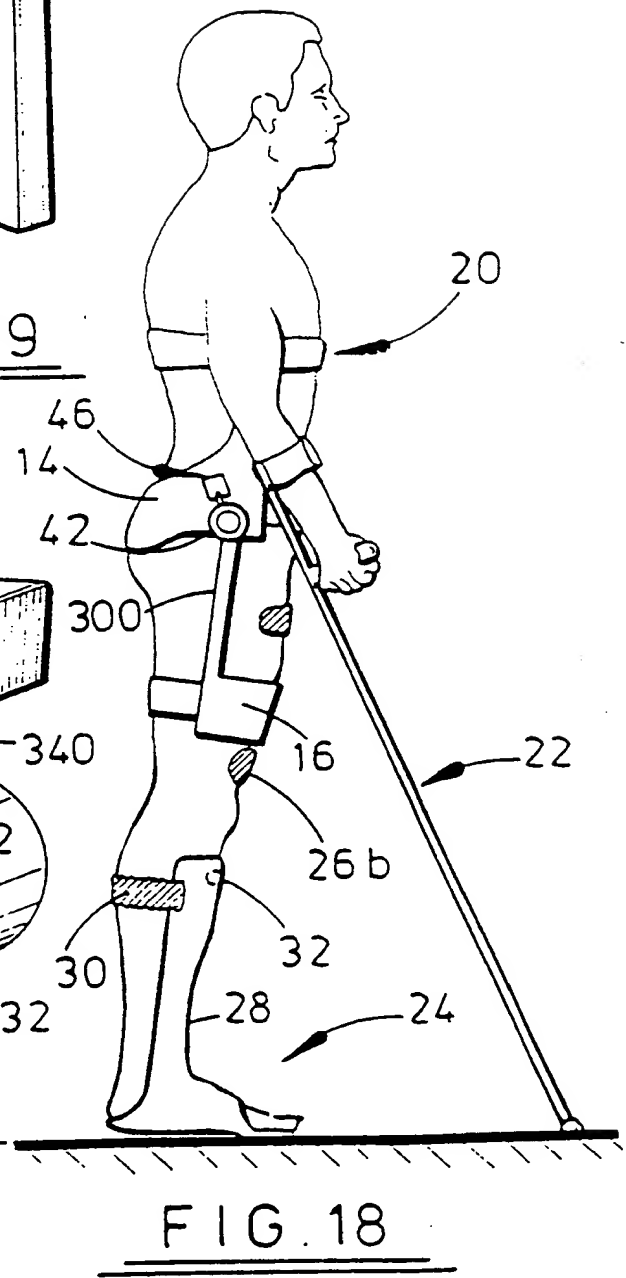
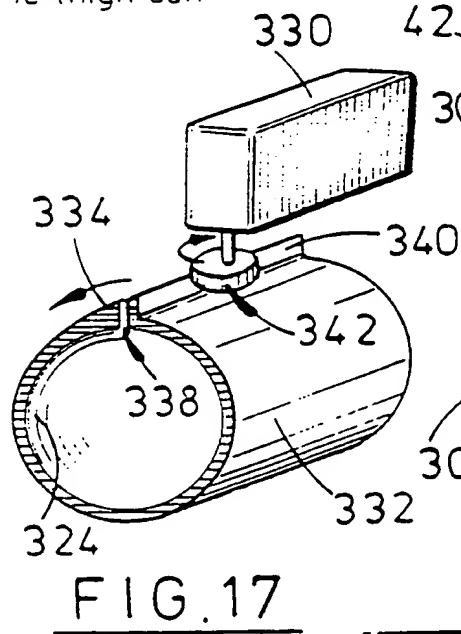


FIG. 16

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To thigh cuff



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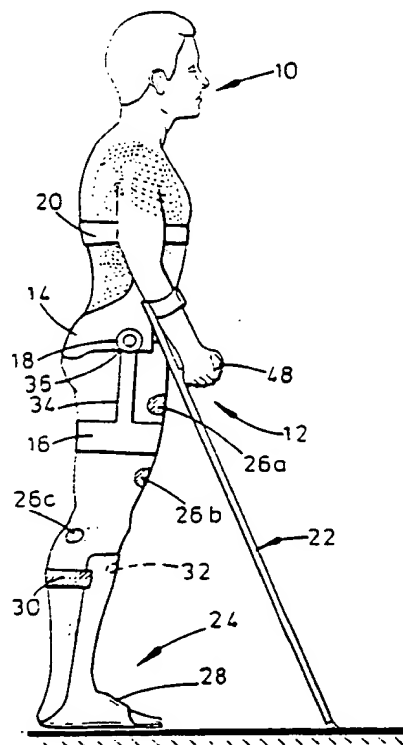
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:

7 July 1994 (07.07.94)

(54) Title: **ORTHOSIS AND PROSTHESIS**

**(57) Abstract**

An orthosis or prosthesis (12) is described which has a first member (34), a second member (14) and a pivotal joint (36) therebetween. The joint (36) includes one-way clutch means based on a wrap spring clutch (42), and a servo (46) arranged to be energised to wrap or unwrap the clutch spring (42) to disengage or engage the clutch (36), the servo (46) being arranged to maintain the clutch (36) in a disengaged condition without continuing energisation of the servo. The orthosis or prosthesis can be applied to a variety of joints such as the hip, knee, ankle, elbow and wrist. Various embodiments of the invention are described.

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/GB 93/02220

A. CLASSIFICATION OF SUBJECT MATTER

A 61 F 2/68, A 61 F 2/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SOVIET INVENTIONS ILLUSTRATED, PQ section, week 8804, issued March 09, 1988 DERWENT PUBLICATIONS LTD., London, SU, 1316 669 (PROSTHESIS RES INST.) . --	1, 6, 14, 15
A	SOVIET INVENTIONS ILLUSTRATED, PQ section, week 8438, issued October 31, 1984 DERWENT PUBLICATIONS LTD., London, SU, A, 1068 117 (AS UKR STRENGTH PROBLEMS) . --	1, 6, 14
A	GB, A, 2 201 260 --	1

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

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Date of the actual completion of the international search

26 January 1994

Date of mailing of the international search report

07.06.94

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

-2-

National Application No.

PCT/GB 93/02220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>(BOX) 24 August 1988 (24.08.88), the whole document. --</p> <p>DE, B, 1 042 176 (HÄFNER) 30 October 1958 (30.10.58), claim 1; fig. 1. ----</p>	1,6

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7, 14-19 (see PCT/ISA/210 (extra sheet))

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

The application shows four different groups of inventions, namely:

- 1.) claims 1 to 7 and 14 to 19 (an orthosis or prosthesis having a pivotal joint including clutch means and a servo for operating the clutch).
- 2.) claims 8 to 10 (an orthosis or prosthesis having a pivotal joint including energy storage means)
- 3.) claims 11 to 13 (a reciprocating gait orthosis having right and left hip joints with extension in one hip and thigh member forces the others)
- 4.) claims 20 to 23 (an orthosis or prosthesis with members coupled by a mechanical coupling and with control means).

First of all the claims 6 to 23 are formally not related to any of the claims 1 to 5 which are formally related to each other. But the claims 6,7 and 14 to 19 fullfill the requirement of unity of invention because they show an evidential technical relationship to the claims 1 to 5 although they are formally not related to claim 1 as mentioned above.

The claims 8 to 10, 11 to 13 and 20 to 23 do not fullfill the requirement of unity because there is no evidential technical relationship to the group 1 (claims 1 to 7 and 14 to 19). For a technical relationship one or more of the same or corresponding special technical features would be necessary. - However the technical features of the four groups of claims do not show any technical relationship to each other. Thus the lack of unity of invention is evident.

ANHANG

zum internationalen Recherchen-
bericht über die internationale
Patentanmeldung Nr.

ANNEX

to the International Search
Report to the International Patent
Application No.

ANNEXE

au rapport de recherche inter-
national relatif à la demande de brevet
international n°

PCT/GB 93/02220 SAE 80993

In diesem Anhang sind die Mitglieder
der Patentfamilien der im obenge-
nannten internationalen Recherchenbericht
angeführten Patentdokumente angegeben.
Diese Angaben dienen nur zur Unter-
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This Annex lists the patent family
members relating to the patent documents
cited in the above-mentioned inter-
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